



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 2, 2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 88965-R
Supplement to Data Package 407483
Product Name: Pathex® Antimicrobial Filter Media

From: Wallace Powell, Biologist
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To: Velma Noble, PM 31/ Cletis Mixon
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: AS Filtration, LLC

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredients:</u>	<u>% by weight</u>
3-(Trihydroxysilyl)propyl dimethyl octadecyl ammonium chloride (EPA PC Code 107403)	0.05
<u>Other Ingredient(s):</u>	99.95
Total:	100.00

BACKGROUND

This memorandum is supplemental to a 3/28/2013 memorandum, Data Package 407483. In response to the findings in that memorandum, the applicant has submitted an attrition resistance test, MRID 491074-01 (EPA received 4/24/2013).

RECOMMENDATION

The attrition resistance test, MRID 491074-01, indicates negligible attrition of particles larger than 44 µm, for each of the three mesh sizes of sand that Pathex uses.

Acute inhalation toxicity. The waiver is acceptable. Acute Inhalation Toxicity Category IV is assigned. The attrition test results are favorable and supplement the previously submitted waiver request.

Eye irritation. Based on the attrition test and the previously submitted leaching data referenced in the waiver request, eye irritation can be expected to be primarily limited to the mechanical irritation of the sand. The attrition test results suggest very limited exposure to very small particles, though more significant exposure to particles much larger than the sieve size in the test may occur. We assign eye irritation Toxicity Category III, indicating mild to moderate hazard.

Summary

The acute toxicity profile of Pathex® Antimicrobial Filter Media is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	476890-03	IV	Cited*
Acute Dermal Toxicity	476890-04	IV	Cited*
Acute Inhalation Toxicity	489922-02 (waiver request) 491074-01 (attrition test)	IV	Waived
Primary Eye Irritation		III	Waived
Primary Skin Irritation	476890-07	IV	Cited*
Dermal Sensitization	476890-08	Non-sensitizer	Cited*

*Because the cited studies are integral to the acceptability of these requests, they are accepted as "Citations" not "Waivers".

Product labeling

The human-hazard Precautionary and First Aid label statements in the submitted labeling (Version 20130425) are acceptable.

The following acute inhalation-related precautions in the submitted labeling are acceptable and optional:

- "Harmful if inhaled. Avoid breathing dust."
- "a NIOSH approved dust mask or respirator if applications result in dusting."
- "Remove and wash contaminated clothing prior to reuse."

The submitted "If Inhaled" and "If Swallowed" First Aid statements are acceptable and optional.

Note: The submitted label states, "First aid and handling precautions are the same as silica sand." We have no adverse comment regarding that statement. However, as we do not regulate labeling for silica sand, we have no comment on whether the statement holds true.